



UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/334,537 | 06/16/99 | ACHARI | R 719-163 |

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HM12/0425

EXAMINER

OKE, V

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED:

04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/334,537 | Applicant(s) ACHARI ET AL. | |
| | Examiner Victor Oke | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 16-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
 2. ☐ received in Application No. (Series Code / Serial Number) ____.
 3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 15) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 19) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

(11) *Response to Argument*

1. Applicant's election with traverse of the invention of Group I, i.e. claims 1-15 drawn to an intranasal morphine formulation in Paper No. 5 submitted February 1, 2000 is acknowledged. On reconsideration, the specie election requirement in the previous office action is withdrawn. The traversal as to the elected invention on the ground(s) that the inventions are related and that they should be included in a single patent. This is not found persuasive because the inventions of Groups I and II are independent and distinct since the method of Group II can be practiced with another materially different product, such as a nalbuphine or naloxone containing composition. Further, the search for the method of Group II is not required for the composition of Group I. Note that the search herein is not limited to the patent files. Therefore the restriction requirement to inventions in the office action mailed November 26 1999 is maintained.

The requirement as to the inventions herein is still deemed proper and is therefore made FINAL.

2. Claims 16-29 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5 submitted February 1, 2000.

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Claim Objections

3. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 recites "further comprising one or more pharmaceutical excipients". It is not further limiting because base claim 8 already recites one or more pharmaceutical excipients. Insertion of the term "additional", in line 2 of claim 9 prior to the term "pharmaceutical" is suggested if applicants intend the addition of more pharmaceutical excipients to the composition of claim 8.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hussain et al. WO Patent Number 82/03768 or US Patent Number 4,464,378. (See the IDS of August 31, 1999).

The prior art teaches a pharmaceutically acceptable nasal dosage form for nasally delivering systemically therapeutic levels of drug e.g., morphine to a warm-blooded animal. See page 5, lines 3-15 in the WO patent or column 2, lines 45-62 in the US patent. The WO patent teaches a 15mg/0.1ml solution (15%) of morphine at pH 4.5. See page 22 example 2 in the WO patent or column 10, example 2 in the US patent.

Claims 1-11 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Merkus US Patent Number 5,756,483.

Merkus teaches a pharmaceutical solution formulation of morphine for nasal delivery employing a morphine pharmaceutical salt at a pH of 6, which also contains applicant's preferred other pharmaceutical excipients, including a preservative, a phosphate buffer, a humectant, and an absorption enhancing agent. See e.g., column 6 lines 37-50 in US Patent number 5,756,483.

Claims 1-11 and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Merkus US Patent Number 5,942,251.

Merkus teaches a pharmaceutical solution formulation of morphine for nasal delivery employing a morphine pharmaceutical salt at a pH of 6, which also contains applicant's preferred other pharmaceutical excipients, including a preservative, a

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phosphate buffer, a humectant, and an absorption enhancing agent. See e.g., column 6, line 62 bridging column 7, line 9.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkus US Patent Number 5,756,483.

Merkus teaches pharmaceutical formulations of morphine for nasal delivery employing morphine pharmaceutical salt at a pH of 6 and applicant's other

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pharmaceutical excipients, including a preservative, a phosphate buffer, various thickening agents, a humectant, an absorption enhancing agent and combinations thereof. See e.g., column 2, lines 55-63, column 6, lines 37-50, column 7 line 63 bridging column 8 line 4 and particularly example 2 (lines 40-50) in column 8.

Merkus does not expressly disclose a composition within the instant claims containing the specified thickening agents and humectants.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the thickening agents and humectants herein in the morphine formulations of Merkus.

A person of ordinary skill in the art would have been motivated at the time the invention was made to employ the specified thickening agents and humectants herein in the pharmaceutical morphine formulation of Merkus because Merkus teaches that these excipient materials are useful in morphine formulations.

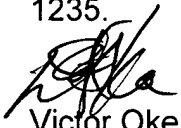
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor Oke whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday to Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D. can be reached on (703) 308-0570. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Victor Oke
3-29-00


MINNA MOEZIE
PRIMARY EXAMINER